

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIODELIVERY SCIENCES INTERNATIONAL,)	
INC. and ARIUS TWO, INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 18-1395 (CFC)
)	
ALVOGEN PB RESEARCH & DEVELOPMENT)	
LLC, ALVOGEN MALTA OPERATIONS LTD.,)	
ALVOGEN PINE BROOK LLC, ALVOGEN, INC.,)	
and ALVOGEN GROUP, INC.,)	
)	
Defendants.)	

~~PROPOSED~~ **STIPULATED PROTECTIVE ORDER**

Pursuant to Federal Rule of Civil Procedure 26(c) and the Scheduling Order, Plaintiffs BioDelivery Sciences International, Inc. and Arius Two, Inc. (collectively, "Plaintiffs") and Defendants Alvogen PB Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook LLC, Alvogen, Inc., and Alvogen Group, Inc. (collectively, "Defendants") request that the following Stipulated Protective Order be entered in the above-captioned case (the "Proceeding") to govern the exchange of discovery material by the parties and third parties, the use or exhibition of documents and things during discovery, and testimony containing trade secrets, confidential or proprietary research, development, technical, financial, strategic, customer, or commercial information, as well as other kinds of commercially sensitive information within the meaning of the Federal Rules of Civil Procedure. Plaintiffs and Defendants (collectively, "the parties") and this Court agree that the disclosure of such commercially sensitive information poses a substantial risk of harm to the legitimate proprietary interests of the parties and third parties. Therefore, good cause exists for entry of this Stipulated Protective Order to preserve the confidentiality of certain documents and information, to outline

procedures and reasonable restrictions on the disclosure of sensitive materials, and to permit discovery to proceed without delay.

Accordingly, the Court hereby enters the following Protective Order, which shall control the disclosure, dissemination, and use of information in this Proceeding:

I. Designation of Confidential and Highly Confidential Information

1. The designation of material as “Confidential Information” as used in this Protective Order means information (regardless of how it is generated, stored, or maintained) or tangible things that qualify for protection under Federal Rule of Civil Procedure 26(c) including but not limited to any trade secrets or other research, development, commercial, personnel, information that is non-public and confidential or proprietary, the value of which arises from its secrecy. Identification of types of documents in this paragraph shall not be an admission by either party that such documents are relevant or admissible in this Proceeding. Confidential Information may be contained in discovery information or materials produced or obtained in this action by or through any means and by or through any person or entity. The Confidential Information contained therein and all copies, recordings, abstracts, excerpts, analyses or other writings that contain, reveal, or otherwise disclose such Confidential Information shall also be deemed Confidential Information.

2. The designation of material as “Highly Confidential” by the producing party constitutes its reasonable, good faith representation that the material disclosed is so sensitive and confidential that the disclosure, whether separately or in conjunction with other information being disclosed, is believed in good faith by the disclosing party to have the potential for causing competitive harm or giving a competitive advantage to others and access to such information should be more limited. Information that may be designated “Highly Confidential” means

information (regardless of how it is generated, stored or maintained) or tangible things that qualify for protection under Federal Rule of Civil Procedure 26(c) that satisfies the requirements of paragraph 1 and which comprises or contains the following particularly sensitive information of the parties and their affiliates: future financial documents (for example, P&L statements), business strategy, projected future sales, pricing, customer/vendor agreements, revenue, cost, or profit information for its products, documents concerning the research and development of any products other than Belbuca[®] or Defendants' generic product at issue in this case, pending patent applications, New Drug Applications other than New Drug Application No. 207932 for Belbuca[®], Abbreviated New Drug Applications other than Abbreviated New Drug Application No. 211594 for Buprenorphine Buccal Film at issue in this case, and any other information a producing party believes in good faith could cause irreparable harm to its business if disclosed to personnel for the receiving party. For avoidance of doubt, the current New Drug Application No. 207932 for Belbuca[®] and Abbreviated New Drug Application No. 211594 and Drug Master File in this case shall not be designated "Highly Confidential" under this order. Identification of types of documents in this paragraph shall not be an admission by either party that such documents are relevant or admissible in this Proceeding.

3. Any party or third party may designate as "Highly Confidential Information" or "Confidential Information" all or any part of any discovery or other materials produced or served in this Proceeding, or filed with the Court, including without limitation, documents and things, pleadings, motions, interrogatory answers, deposition testimony, and responses to requests for admission, which contain sensitive proprietary, business, financial, technical, or other confidential information or know-how protectable under Federal Rule of Civil Procedure 26, as set forth in paragraphs 1 and 2 above.

4. A party or third party shall designate a document or thing as Confidential Information by marking it prominently on its face with the legend “CONFIDENTIAL INFORMATION” or “CONFIDENTIAL INFORMATION—SUBJECT TO PROTECTIVE ORDER” when it is produced to the party seeking discovery. A party or third party shall designate a document or thing as Highly Confidential Information by marking it prominently on its face with the legend “HIGHLY CONFIDENTIAL INFORMATION” or “HIGHLY CONFIDENTIAL INFORMATION—SUBJECT TO PROTECTIVE ORDER” when it is produced to the party seeking discovery. Anything that cannot be so marked on its face shall be marked by placing the appropriate legend on a container or package in which the thing is produced or on a tag attached thereto. In addition, each page of each document and each thing produced pursuant to discovery in this Proceeding shall bear a unique identifying number.

5. Any response to written interrogatories or requests for admission or any testimony adduced at a deposition upon written questions in this litigation that constitutes or contains Confidential Information or Highly Confidential Information shall be labeled or marked with the legend “CONTAINS CONFIDENTIAL INFORMATION—SUBJECT TO PROTECTIVE ORDER” or “CONTAINS HIGHLY CONFIDENTIAL INFORMATION—SUBJECT TO PROTECTIVE ORDER” as appropriate by the party providing the response or testimony on the first page of that document near the caption.

6. Notwithstanding such designation, Confidential Information and Highly Confidential Information does not include information obtained independently of this Proceeding as to which no obligation of confidentiality applies. Accordingly, nothing in this Order shall prevent any person, including a Qualified Person, from making use of any information that is designated as Confidential Information or Highly Confidential Information if such information:

a. was lawfully in his or her possession prior to receiving the information or document under the provisions of this Protective Order,

b. was, is, or becomes available to the public through no fault of a receiving party,

c. is disclosed by a third party who is not subject to any confidentiality obligations at the time of the disclosure, or

d. is discovered independently by the receiving party by means that do not constitute a violation of this Protective Order.

7. Nothing in this Protective Order shall prevent a party or third party from redacting from documents or things, which otherwise contain relevant discoverable information, any Confidential Information or Highly Confidential Information that is irrelevant to this Proceeding or otherwise not discoverable pursuant Federal Rule of Civil Procedure 26(b).

8. Prior to production, a party or third party may redact from all documents, e-mails, and personal electronic files all personal information, including the following: home address, home and cell phone numbers, pager numbers, names of spouses and children, credit card information, benefits information, compensation information, and any nonresponsive information found in employee files.

9. Unless otherwise agreed by the parties, deposition transcripts taken in connection with this Proceeding will be temporarily designated and treated as Highly Confidential Information and marked on its first page with the legend "HIGHLY CONFIDENTIAL — SUBJECT TO PROTECTIVE ORDER." A deponent may review the transcript of his or her deposition at any time. Nothing in this paragraph shall prevent a party from showing to its own

employees, officers, directors, or agents transcripts from depositions taken of its own fact witnesses.

10. Any material provided for inspection, as opposed to documents produced outright, in this Proceeding is to be treated by the inspecting/receiving party as Highly Confidential Information pending the copying and delivery of any copies of the same by the producing party. After copies are delivered to the inspecting/receiving party, the information in such documents or things will be treated consistent with any legend on each document or thing. Unless otherwise agreed or ordered by this Court, inspection of documents or things by a party shall be conducted only by Outside Counsel eligible under paragraph 14(a) below.

11. Documents and things produced without a legend designating the material Confidential Information or Highly Confidential Information shall not be subject to this Protective Order, unless otherwise agreed by the parties or ordered by the Court.

II. Use of Confidential and Highly Confidential Information

12. Confidential and Highly Confidential Information, including all copies, summaries, abstracts, excerpts, indices, and descriptions of such material, shall be held in confidence by the receiving party, shall be used only by persons permitted access to the information under this Protective Order, and shall not be used for any purpose other than in connection with this Proceeding, any appeal therefrom, and remands thereto. For the avoidance of doubt, no party or person, who receives Confidential and/or Highly Confidential Information under this Protective Order, shall make any other use of such Confidential and/or Highly Confidential Information, including but not limited to use for commercial or competitive purposes or use in any other legal proceeding or administrative action, including but not limited to proceedings or actions before the U.S. Patent & Trademark Office, the FDA, the United States

Pharmacopeia, and all similar foreign or domestic agencies, except as permitted by order of the Court or otherwise agreed upon in writing by the parties. Nothing contained in this Protective Order shall preclude any party from using its own Confidential and/or Highly Confidential Information in any manner it sees fit, without prior consent of any party or the Court. Nothing in this Protective Order shall restrict any party's counsel from rendering advice to its clients with respect to this Proceeding and, in the course thereof, relying upon Confidential and/or Highly Confidential Information, provided that in rendering such advice counsel shall not disclose any other party's Confidential and/or Highly Confidential Information other than in a manner provided for in this Protective Order.

III. Access To Confidential Information

13. Confidential information may be disclosed only to the following "Qualified Persons:"

a. Persons entitled to receive Highly Confidential information as identified and described in paragraph 14, and

b. ***In-House Counsel:*** Each party may designate up to two in-house counsel, as well as the secretarial and clerical employees who work regularly with such in-house counsel, to receive Confidential Information (but not Highly Confidential Information) subject to the following restrictions:

i. Each in-house counsel designated pursuant to this paragraph must acknowledge receipt and understanding of this Protective Order, agree to be bound thereby, agree to use the Confidential Information solely for this litigation and not to disclose any Confidential Information to any other person or entity in violation of this Protective Order, never to use any Confidential Information, directly or indirectly, in competition with the producing

party or for prosecuting any patent or patent application, for patent licensing, or for communications with or before the FDA or the United States Pharmacopoeia, and all similar foreign or domestic agencies, nor to allow any other person to do so, and execute a declaration acknowledging the foregoing, in the form annexed hereto as Exhibit A. Outside counsel shall forward a copy of the executed declaration to counsel for the producing party at least ten (10) business days prior to the disclosure of Confidential Information to such in-house counsel.

ii. Any party has the right to substitute a new person for in-house counsel designated under this paragraph one time provided that: (a) at any time no more than two designated in-house counsel for each side shall have access to Confidential Information pursuant to this Protective Order; and (b) such new in-house counsel must acknowledge receipt and understanding of this Protective Order; agree to be bound thereby; meet all requirements set forth in this paragraph; and execute a declaration acknowledging the foregoing, in the form annexed hereto as Exhibit A, a copy of which will be forwarded to opposing counsel (along with the title, business address, and job description), at least ten (10) business days prior to the disclosure of Confidential Information to such substitute in-house counsel. If a party objects in writing to a proposed designated in-house personnel within ten (10) business days after receipt of such notice of it, the disclosure may not be made without prior approval by the Court or an express written agreement between the parties removing the objection. Although the burden shall be on the objecting party to show the Court why the proposed in-house counsel does not satisfy the requirements of this paragraph and why the disclosure should not be allowed, the proposing party has the burden of providing sufficient information on all topics described in this paragraph for the Court to reasonably make that determination. Parties may only substitute in-

house counsel one time during the litigation. Additional substitutions shall be permitted only for good cause shown and shall not be unreasonably withheld.

c. In-house counsel shall be granted access to confidential information as provided herein immediately after execution of this Stipulated Protective Order and their respective execution of Exhibit A.

IV. Access To Highly Confidential Information

14. Highly Confidential Information may be disclosed only to the following:

a. ***Outside Counsel:*** Attorneys of record in the Proceeding, and their staff, from the law firms of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP; Morris, Nichols, Arsht & Tunnell LLP; Leydig, Voit & Mayer, Ltd.; and Heyman, Enerio, Gattuso & Hirzel LLP.

b. ***Litigation Support:*** Independent litigation support service personnel, including copy vendors, litigation consultants, outside exhibit or demonstrative preparation companies, or litigation study groups retained by a party for litigation support in connection with this Proceeding, provided that such persons or entities agree to maintain the confidentiality of Confidential and/or Highly Confidential Information, and provided that such personnel are not engaged in the research, development, manufacture, marketing, or sale of pharmaceutical products;

c. ***Experts:*** Independent consultants or experts assisting Outside Counsel, provided such consultants or experts each agree to comply with the requirements of this Protective Order, and sign a copy of Exhibit A to this Protective Order;

d. ***Court:*** The Court and any members of its staff to whom it is necessary to disclose Confidential and/or Highly Confidential Information for the purpose of assisting the

Court in this Proceeding, as well as court reporters or typists for the sole purpose of recording, or transcribing testimony, documents, or information relating to this Proceeding;

e. ***Court Reporters & Videographers:*** Independent court reporters, videographers, interpreters, and translators, and their staff, for the sole purpose of recording, transcribing, or translating testimony or documents relating to this Proceeding.

15(a). Any individual who receives access to Confidential Information and/or Highly Confidential Information may not be involved in the future “prosecution” of patents or patent applications concerning any pharmaceutical film formulation containing buprenorphine for use in the treatment of pain, including without limitation, any patent application claiming priority to the patents asserted in this Proceeding, before any foreign or domestic agency, including the United States Patent & Trademark Office, and will remain so excluded from the time of receipt of Confidential Information and/or Highly Confidential Information until the period ending one (1) year after final termination of this Proceeding, including any appeals thereof. For purposes of this Protective Order, “prosecution” means substantive involvement in drafting or amending the scope of patent claims. “Prosecution” does not include representing a party before a domestic or foreign patent agency in any reissue, interference, *inter partes* review, post-grant review, or reexamination proceeding. The designated in-house counsel may be involved in the supervision of other attorneys who engage in prosecution activities, as long as the in-house counsel receiving the Confidential Information is not providing guidance to those they supervise regarding the drafting or amending the scope of patent claims concerning any pharmaceutical film formulation containing buprenorphine for use in the treatment of pain.

15(b). Notwithstanding any other provision of this Protective Order, and to avoid any doubt, in-house counsel designated pursuant to paragraph 13 are permitted access to Highly

Confidential information if, and only if, such Highly Confidential information is (1) used in any deposition or attached to any deposition transcript or (2) attached to any document filed with the Court.

16. The disclosure of Confidential and/or Highly Confidential Information under this Protective Order is further subject to the following restrictions, which shall remain in effect for one (1) year after final termination of this Proceeding, including any appeals thereof:

a. The individuals who have received access to Confidential and/or Highly Confidential Information may not directly participate in scientific experiments (e.g., clinical testing or laboratory work) relating to Belbuca® or Defendants' generic product at issue in this case. For the avoidance of doubt, nothing herein prevents such individuals from participating in scientific experiments conducted specifically for the purposes of this litigation.

b. The individuals who have received access to Confidential and/or Highly Confidential Information may not use that Confidential and/or Highly Confidential Information for any purpose other than this litigation, including, but not limited to patent licensing or for communications with or before the U.S. Patent & Trademark Office, FDA, the United States Pharmacopoeia, or any similar foreign or domestic agency.

17. Only Qualified Persons, the deponent, and his or her attorney (if any), shall be allowed to attend any portion of a deposition in which Confidential and/or Highly Confidential Information is used or elicited from the deponent. Counsel for the designating party may request that all persons other than the witness, counsel for the witness (if a third party witness), and any Qualified Persons, leave the deposition room for any portion of a deposition during which examination is conducted concerning Confidential and/or Highly Confidential Information by the designating party. The failure of individuals other than those specified in the previous sentence

to leave the deposition room during any portion of the deposition which inquires into matters deemed Confidential and/or Highly Confidential Information by the designating party shall constitute justification for counsel to instruct the witness that he or she shall not answer the question(s) posed concerning such matters.

18. This Protective Order shall not limit a party's examination, at a deposition, hearing, or trial, of persons who are not authorized to receive Confidential and/or Highly Confidential Information under the terms of this Protective Order, so long as such examination concerns Confidential and/or Highly Confidential Information that the witness authored, received, was involved in the subject matter described therein, previously had access to or knowledge of, or is a present employee of the party that produced the information, document or thing, as demonstrated by the information itself or by foundation testimony during a deposition, hearing, or trial or if the producing party consents to such disclosure. This Protective Order shall not prevent counsel from examining a witness in a good-faith effort to determine whether he or she authored, received, or previously had access to or knowledge of Confidential and/or Highly Confidential Information.

19. Before disclosing another party's Confidential and/or Highly Confidential Information to any outside consultant or expert under paragraph 14(c), the party shall first provide to the producing party (a) a signed copy of the declaration found in Exhibit A of this Protective Order, (b) a current resume (*curriculum vitae*) for the consultant or expert, and (c) a list of any other cases in which the consultant or expert has testified as an expert at trial or by deposition within the preceding four (4) years. Once the producing party has received the requisite documents and consultant/expert information, the producing party shall then have seven (7) calendar days to provide a written objection to the proposed disclosure of its Confidential

and/or Highly Confidential Information, including the specific reason(s) for such objection. If a timely written objection is made, (a) there shall be no disclosure of the Confidential and/or Highly Confidential Information to the consultant or expert, except by further order of the Court or by agreement by the parties, (b) the parties agree to promptly meet and confer in good faith regarding the basis for (and resolution of) the objection, and (c) if the parties cannot reach an agreement, the party objecting to the disclosure of information to the consultant/expert may raise the issue with the Court within five (5) calendar days of the meet and confer. To the extent the issue is brought to the court pursuant to this paragraph, the objecting party shall bear the burden of showing why disclosure of information to that consultant/expert should be precluded. Failure to timely object or to timely raise the objection with the Court will act as a waiver of the objection, and the consultant or expert will become a Qualified Person.

V. Challenging or Changing the Designation of Confidential and/or Highly Confidential Information

20. Any producing party may change a designation to Confidential and/or Highly Confidential Information (or withdraw a designation) regarding any material that it has produced by notifying counsel for each party in writing. Upon receipt of such notice, the non-producing party shall: (a) not make any further disclosure or communication of such newly designated material except as provided for in this Protective Order; (b) take reasonable steps to notify any persons known to have possession of any material with the original designation (or lack of designation) and alert those persons of the effect of such a change in designation under this Protective Order; and (c) promptly retrieve or have destroyed all copies and transcriptions of such originally designated (or undesignated) material from any persons known to have possession of such material who are not Qualified Persons under paragraphs 13 and 14 in light of the change of designation. With respect to (c) above, for documents originally lacking a

Confidential and/or Highly Confidential Information designation, the copies and transcriptions of such documents shall be collected from any persons or entities who are not Qualified Persons, or, alternatively, copies and transcriptions of such documents shall be destroyed. Properly marked documents, reflecting the new designation, shall be promptly provided by the producing party.

21. A party receiving documents or things shall not be obligated to challenge the propriety of a Confidential and/or Highly Confidential Information designation (or redesignation) at the time the document or thing is produced, and a failure to do so shall not preclude a subsequent challenge thereto. If a receiving party disagrees at any time with a Confidential and/or Highly Confidential Information designation made by another party or a third party, the following procedure shall be used:

a. The party seeking to change the designation on another party's documents or things shall provide the producing party or third party a written notice specifying the documents, things, or information for which a change in designation is sought, and the reasons for the request. The producing party or third party shall have seven (7) calendar days after receipt of the written notice within which to object in writing to the change in designation or removal of protection afforded by this Protective Order and to specify why protection under this Protective Order is appropriate.

b. If the producing party or third party objects in writing within seven (7) calendar days of receiving such a written notice, both parties shall meet and confer to attempt to resolve the dispute without involvement of the Court.

c. If the parties or third parties cannot reach agreement concerning the change in designation, the party seeking the removal of protection for the Confidential and/or Highly Confidential Information shall raise the issue with the Court.

d. The parties shall continue to treat the document(s) or thing(s) at issue as Confidential and/or Highly Confidential Information (according to the original designation(s)) until the dispute is resolved by order of this Court, or by agreement of the parties and/or the third party.

e. To the extent any issues are raised with the court arising out of the designation of any material as Confidential and/or Highly Confidential Information under this Protective Order, the burden of justifying the designation shall lie with the producing party or third party.

VI. Inadvertent Production or Use of Confidential and/or Highly Confidential Information

22. Inadvertent production of any document, thing, or information without a designation of Confidential and/or Highly Confidential Information will not be deemed to waive a later claim as to its confidential nature, or stop the producing party from designating said document or information as Confidential and/or Highly Confidential Information at a later date.

23. If Confidential and/or Highly Confidential Information is used inadvertently during the course of the Proceedings (including at depositions) inconsistent with or in contravention of other provisions of this Protective Order, the information shall not lose its confidential status through such use, and counsel shall exercise their best efforts and take all steps reasonably required to protect its confidentiality after such inadvertent use. If Confidential and/or Highly Confidential Information is inadvertently disclosed to a deposition witness, and the witness has testified that they have knowledge concerning that information, the witness may be examined and cross-examined with respect to the document or information disclosed for the remainder of the deposition.

24. If Confidential and/or Highly Confidential Information is disclosed to any person other than in the manner authorized by this Protective Order, the party responsible for the disclosure shall within five (5) calendar days of learning of such disclosure inform the producing party of all pertinent facts relating to such disclosure. As soon as possible thereafter, the parties shall also use reasonable efforts to obtain the prompt return of any such Confidential and/or Highly Confidential Information, and obtain signed a declaration attached hereto as Exhibit A from each unauthorized person or party who received Confidential and/or Highly Confidential Information. The requirements set forth in this paragraph shall not prevent the producing party from requesting that the party responsible for the inadvertent disclosure take additional remedial steps and/or applying to the Court for additional relief.

VII. Inadvertent Production Or Use of Privileged Information

25. If information subject to a claim of attorney-client privilege, attorney work product immunity, or other legal privilege protecting information from discovery is inadvertently produced in any way, such production shall not constitute a waiver (subject matter or otherwise) of any claim of privilege, work product immunity, or other ground for withholding production to which the producing party, third party, or other person otherwise would be entitled. The protections afforded inadvertent production herein shall be at least those provided in Federal Rule of Civil Procedure 26(b)(5)(B) and/or Federal Rule of Evidence 502.

26. If a written claim of inadvertent production of privileged information is made by a producing party to a receiving party, the receiving party shall:

a. immediately upon receipt of the claim not make any further copies, reproductions, or transcriptions of the inadvertently disclosed information or document; if the inadvertent disclosure is discovered during a deposition, the claim for inadvertent production

may be made orally, and upon such oral claim all copies of the requested document physically at the deposition must be immediately returned at the deposition; and

b. within five (5) business days of receipt of the claim described in paragraph (a) above, destroy or return to the supplying party every original and every copy, reproduction, or transcription of all such inadvertently produced information or documents possessed by the receiving party and by those persons to whom the receiving party may have disclosed such information.

27. Recognizing the need for the parties to prepare for their cases based on the discovery that is produced, if any information, document, or thing is used openly in the case, e.g., at a court hearing, in a deposition, as an exhibit to a motion, or is referenced in an expert report or pretrial order, any claim of inadvertent production based on privilege, must be made within two weeks after such use.

28. Nothing herein shall prevent the receiving party from challenging the propriety of the attorney-client privilege, work product immunity, or other privilege designation, or from presenting the information to the Court under seal for a determination of the privilege claim through a written challenge to the Court. The receiving party must preserve the confidentiality of the document or information until the claim is resolved.

VIII. Production or Disclosure of a Third Party's Information

29. Any subpoena or other notice to a third party requesting production of documents shall include a copy of this Protective Order.

30. If a third party produces documents pursuant to a subpoena or other request issued by one of the parties (or by Court order) and if the third party has not requested its documents be treated as Confidential and/or Highly Confidential Information, then it shall be presumed that the documents produced contain information for which the third party has determined require no

designation under the Stipulated Protective Order. The third party's documents and things shall be handled by all parties to this Proceeding according to the appropriate designations under this Stipulated Protective Order. The party issuing the subpoena or other request for documents or things to the third party shall provide any non-requesting party an opportunity to review and make copies of any documents produced in response to that subpoena or request.

31. A party in this Proceeding may temporarily withhold production of otherwise discoverable information sought in a discovery request (e.g., interrogatory, request for production, request for admission) if the party is under an obligation to a third party not to disclose such information (e.g., by prior agreement of confidentiality). In such an event (except for information subject to another protective order or confidentiality order by another court), the producing party shall:

a. timely serve a written objection to the production of the requested information on the basis of its obligation to a third party not to disclose such information;

b. promptly provide to the third party whose confidentiality interests are implicated (i) notice of the pending request to disclose the information, and (ii) a copy of this Protective Order; and

c. if the third party does not agree to disclosure of its information, then the party requesting the documents or things from the third party may (i) serve a subpoena on the third party, if the requesting party has not already done so, or (ii) raise the issue of compelling production of the requested documents against a party and/or third party in the appropriate Court.

32. Any party to this Proceeding that receives a subpoena or other request from a third party that seeks the disclosure/production of Confidential and/or Highly Confidential Information already disclosed in this Proceeding that the party did not itself produce shall give

prompt telephonic and written notice to that original producing party of such subpoena or other notice, but in no event more than seven (7) calendar days after of service of the subpoena or other notice. If the original producing party opposes disclosure of its documents called for by the subpoena or other request, then the party served with the subpoena shall not disclose the pertinent information until a Court has resolved the issue. Absent a Court order, production or disclosure of another party's information shall not be made until the original producing party has agreed to such production to a third party. The original producing party shall bear the burden to oppose, if it deems appropriate, the subpoena or other request on the grounds of confidentiality. This paragraph shall not apply to disclosure of information pursuant to a third party's subpoena or request for Confidential and/or Highly Confidential Information, if the party receiving the subpoena or request itself produced the documents or things called for by the subpoena or request, *i.e.*, this paragraph shall not apply to the disclosure of a party's own documents or things.

IX. Use of Confidential and/or Highly Confidential Information in Filings and in Open Court

33. Nothing herein shall be construed to affect in any manner the admissibility at trial of any document, testimony, or other evidence.

34. The Clerk of Court is directed to maintain under seal any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court in compliance with Local Rule 5.1.3, which has been designated, in whole or in part, as containing or revealing Confidential and/or Highly Confidential Information under this Protective Order.

35. In the event that a party or third party wishes to use any Confidential and/or Highly Confidential Information in any pleading, motion, brief, memorandum, exhibit, affidavit,

declaration, transcript, response to a discovery request, or other paper filed with the Court to be maintained under seal, such paper shall be enclosed in a sealed envelope or other appropriate container. The outside of the sealed envelope or other appropriate container shall state and include:

- a. the caption of this case, including the case number;
- b. the title of the enclosed document;
- c. the name of the party or third party entity filing the document (if the filing entity is not of record in the case, also include a contact name, telephone number, and e-mail address); and
- d. the following legend:

CONTAINS CONFIDENTIAL AND/OR HIGHLY
CONFIDENTIAL INFORMATION PURSUANT TO
PROTECTIVE ORDER: This envelope [or container] is sealed
pursuant to court order and contains confidential information. The
contents of this envelope [or container] must not be shown to any
person except as authorized by the Protective Order in this action.

X. Disposition of Confidential and/or Highly Confidential Information After Conclusion of This Proceeding

36. Upon the final non-appealable termination of this Proceeding, all Confidential and/or Highly Confidential Information received from an opposing or third party (and all copies and transcriptions thereof), shall be destroyed or returned to the producing party within ninety (90) calendar days. Outside counsel, however, may retain (even if such documents or things contain Confidential and/or Highly Confidential Information) all correspondence, pleadings and exhibits, deposition transcripts and exhibits, expert reports and exhibits, hearing and trial transcripts and exhibits, court-filed documents and exhibits, and all documents and things containing or reflecting attorney work product. Documents and work product retained by Outside Counsel shall remain subject to the terms of this Protective Order. Pursuant to this paragraph, then, after ninety (90) calendar days following final non-appealable termination of

this Proceeding, no person or entity other than Outside Counsel shall retain any Confidential and/or Highly Confidential Information that it received from another party during the course of the Proceeding, including but not limited to Confidential and/or Highly Confidential Information in the form of notes, recordings, memoranda, summaries or other written materials relating to or containing another party's Confidential and/or Highly Confidential Information.

XI. Additional Provisions

37. This Order shall be binding upon the parties to this Proceeding and signatories to the Certification, including their successor(s) and assigns, and their respective attorneys, agents, representatives, officers, and employees.

38. This Order shall apply to all information and material produced in this Proceeding, including all previously produced information and material prior to the execution of this Protective Order by the Court.

39. The parties agree that the following documents will not be discoverable: (a) drafts of expert reports, affidavits, or declarations; (b) counsel's communications with experts, affiants or declarants regarding such draft documents or final reports, affidavits, or declarations, except to the extent such communications are excepted by Federal Rule of Procedure 26(b)(4)(C)(i)-(iii); and (c) experts' affiants', and declarants' notes and working papers regarding such documents.

40. If any party breaches, or threatens to commit a breach, of any of the provisions of this Protective Order, each non-breaching party or third party that produced information subject to this Protective Order shall have the right to ask the Court for any remedies available under law or in equity, including having the Protective Order specifically enforced (without posting any bond) and/or entering a restraining order or injunction (preliminary or permanent) against the breaching party for breaches, threatened or actual. It is agreed and acknowledged that, in the

event of any such breach or threatened breach, the breaching party is not entitled to a presumption that money damages or legal remedies are sufficient or adequate to remedy such a breach.

41. By written agreement of the parties, or upon order of the Court, the terms of this Protective Order may be amended or modified, provided that any such stipulated modification concerning the use of Confidential and/or Highly Confidential Information shall be presented to the Court.

42. This Protective Order shall continue in force until amended or superseded by express order of the Court. This Protective Order shall survive termination of this Proceeding, including any final judgment, appeal, or settlement to the extent the Confidential and/or Highly Confidential Information is not or does not become known to the public.

43. Nothing in this Protective Order shall prejudice the right of any party or third party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality.

44. In the event that a new party is added, substituted, or otherwise brought into this Proceeding, this Protective Order will be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of this Protective Order.

45. A legible photocopy of a document may be used as the “original” for all purposes in this Proceeding unless under the circumstances it would be unfair to admit the duplicate in lieu of the original (*see* FRE 1003(2)).

46. Each person or entity who receives any Confidential and/or Highly Information agrees to subject himself/herself to the jurisdiction of this Court for the purpose of any

proceedings relating to the performance under, compliance with, or violation of this Protective Order.

47. Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

48. In order to expedite the discovery process, until this Protective Order has been entered by the Court, the parties agree that after counsel for the parties execute this Protective Order, it will be treated as though it had been "So Ordered."

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

HEYMAN ENERIO GATTUSO & HIRZEL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
jtigan@mnat.com
Attorneys for Plaintiffs

/s/ Dominick T. Gattuso

Dominick T. Gattuso (#3630)
200 Delaware Avenue, Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@hegh.law
Attorney for Defendants

March 22, 2019

SO ORDERED this 28th day of March, 2019.



UNITED STATES DISTRICT JUDGE

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BIODELIVERY SCIENCES INTERNATIONAL,)	
INC. and ARIUS TWO, INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 18-1395 (CFC)
)	
ALVOGEN PB RESEARCH & DEVELOPMENT)	
LLC, ALVOGEN MALTA OPERATIONS LTD.,)	
ALVOGEN PINE BROOK LLC, ALVOGEN,)	
INC., and ALVOGEN GROUP, INC.,)	
)	
Defendants.)	

CERTIFICATION REGARDING PROTECTIVE ORDER

1. I, _____ have been asked by counsel for Plaintiffs / Defendants [circle one] in the above-captioned matter to review certain confidential documents or other information that is subject to the Stipulated Protective Order that has been or will be entered by the District Court for the District of Delaware in the above captioned case.

2. My present employer is _____ and the address of my present employer is _____
_____. My present occupation or job title/description is _____
_____.

3. I have received a copy of the Protective Order in this action. I have carefully read and understand its provisions.

4. I will comply with all provisions of the Protective Order, including but not limited to the following:

a. I will not disclose any information, documents, or things designated as Confidential and/or Highly Confidential Information under the Protective Order to anyone other than those persons specifically authorized by the Protective Order.

b. I will not use any Confidential and/or Highly Confidential Information except as expressly authorized in the Protective Order.

c. When requested to do so, I will return all materials containing Confidential and/or Highly Confidential Information, and all documents and things that I have prepared relating thereto.

5. I will take reasonable steps to restrict access to any Confidential and/or Highly Confidential Information to only those persons authorized by the Protective Order to have such access. I will inform any of my employees or staff who encounter Confidential and/or Highly Confidential Information of the terms of the Protective Order.

6. I understand that my obligations regarding Confidential and/or Highly Confidential Information under the Protective Order apply equally to copies, summaries, excerpts, transcripts, indices, expert reports, or compilations of information *containing* Confidential and/or Highly Confidential Information, as well as any knowledge or information *derived from* any such information I receive during this action.

7. I understand that if I violate the provisions of the Protective Order, I will be subject to sanctions by the Court, and that the parties or third-parties that designated the information as Confidential and/or Highly Confidential Information may assert other remedies against me.

8. I voluntarily submit to the jurisdiction of the United States District Court for the District of Delaware with respect to the enforcement of the Protective Order, or with respect to

any other order issued by the Court governing the use of Confidential and/or Highly Confidential Information.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: _____
